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I, LEANNE MYNOTT, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. PP 6056 for a patent by WOLFE RESEARCH PTY LTD filed on 22 September 1998.

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Eighth day of October 1999

L. Mynott

LEANNE MYNOTT
TEAM LEADER EXAMINATION
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PROVISIONAL SPECIFICATION

Invention Title: MEDICAL IMPLANT SYSTEM

The invention is described in the following statement:

M1050 1 0 22 SEP 98

MEDICAL IMPLANT SYSTEM

Field of the Invention

The invention relates to a system which facilitates monitoring, treatment and stimulation of a living body. More particularly, this system relies upon the use of electromagnetic waves as the means of transmission of energy and signals between an device implantable inside the living body and an external control device.

Background to the Invention

A number of people all over the world lose their natural ability to control their muscle contraction and are thus physically disabled. Functional Electrical Stimulation (FES) is a technique which incorporates the stimulation of muscles for providing functionality to people suffering from neuromotor control disorders or have otherwise lost their natural ability to control and contract their muscles usefully. The disorder or loss of natural ability can arise through a range of causes, including disease, trauma or stroke.

FES devices can be classified into two categories - implants and external. External FES devices include some simple devices such as those used to correct drop foot, and have been in use for a few decades. The implantable devices are relatively new and the first commercialisation of such a device took place in 1997.

In the present art, implantable devices consist of a controller and a set of up to 16 electrodes connected by wires which run inside the body (Memberg, Peckham, Keith, "A Surgically Implant Intramuscular Electrode for An Implantable Neuromuscular Stimulation System", IEEE trans.Rehab.Eng, vol. 2, no.2, Jun 1994). In this art, the device does not have any internal power source but it is powered by an oscillating magnetic field from the power source coupled with the secondary pick up coil implanted within the patient as a component of the device.

FES devices have been reported which provide this format (US Patent No. 5,358,514 to Schulman et al; Matjacic et al "Wireless Control of Functional Electrical Stimulation Systems", PMnD:9148704, UI:97205715; Sawan, Hassouna et al "Stimulator Design and Subsequent Stimulation Parameter Optimization for Controlling Micturition and Reducing Urethral Resistance", IEEE trans. Rehab.Eng., vo1.4, no.l, Mar 1996). In these devices,

each of the muscle stimulating electrodes is addressable individually. The devices reported have employed frequencies of the magnetic field between 400 K Hz to 50 M Hz.

It is an intrinsic limitation of such magnetic technologies that the source of the oscillating magnetic field must be close to the pick up coil to efficiently transfer energy because of the low permitivity of the body tissues.

Some FES systems reported in the prior art provide the forward loop control for the muscles. Devices have been designed which record information from the extremities - either by recording neural activity or by using sensors (like pressure or vibration etc.) and feedback this information to the controller (Haugland, Hoffer et al "Skin Contact Force Information in Sensory Nerve Signals Recorded by Implanted Cuff Electrodes", IEEE trans.Rehab.Eng.,vol.2, no.l, Mar 1994). Some difficulties associated with these techniques are that the information is unnatural as the subjects have to learn to react to this information, and the invasive nature of their implementation.

Available devices like the Drop Foot FES system automatically restore the gait of the subject and are not under the conscious control of the subject. FES systems like grasp control devices and other similar systems work under the linear control of the subject. These latter devices have a number of drawbacks which that total visual attention of the subject is required. making the application of the device extremely restrictive and that these devices are not intelligent, unlike the body which has a Peripheral Neuromotor control mechanism which works along with the Central Neural System (CNS). Thus subjects fitted with the FES devices have to use their CNS to monitor and control the muscle contraction.

A number of researchers have proposed systems which provide feedback to the subjects (Haughland, Hoffer et al, "Skin Contact Force Information in Sensory Nerve Signals Recorded by Implanted CuffElectrodes", IEEE trans. Rehab. Eng. vo1.2, no. 1, Mar 1994; Hoffer JD, "Closed Loop, Implanted Sensor, Functional Electrical Stimulation System for Partial Restoration of Motor Functions", US Patent No. 4,750,499). These systems primarily utilise invasive methods like recording the neural activity, embedding sensors inside the body or fixing them on the surface of the body. These techniques are highly invasive and also restrictive to the subjects.

Accordingly, investigations were carried out to simplify these known highly invasive techniques. In particular, it was felt that if a better medium could be developed to communicate between the external control and the internal devices, it may be possible to avoid or limit the use of wires in the body and also permit monitoring, treatment and stimulation devices to be placed deeper and more locally to the area of interest in the body.

Description of the Invention

It was discovered that there is a window in the electromagnetic spectrum where the radiation penetrates flesh with little loss. This permits the transmitter to be separated a convenient distance from the receiver that is many times the separation permitted by coupled magnetic fields.

Accordingly, there is provided a system for transmission of power and/or information between a first location external of a living body and a second position internal of the living body which comprises:

(a) a primary control including a power source and a transmitter locatable at the first location; and

(b) an antennae based device locatable at the second position to receive an output from the transmitter,

wherein the power source is adapted to emit high frequency electromagnetic radiation.

In particular, the preferred range of high frequency electromagnetic radiation is between 0.5 to 5 GHz, more preferably 0.8 to 2.5 GHz. This high frequency electromagnetic radiation is receivable by the antenna on the implanted device and used as a source of electrical energy to power the device as well as being capable of carrying an information signal to operate the implanted device.

It was surprisingly found that the use of high frequency electromagnetic radiation allows significant spatial separation of the power source and the implanted device. As such it potentially avoids wires to implanted devices such as stimulating electrodes and permits a number of devices to be implanted deep in the body. It was also found that frequencies the between 0.5 to 5 GHz permitted the use of antennae that were small enough to conveniently implant but still to permit significant penetration into the body. The antennae

format may be a dipole, or loop but the orientation between the transmitter and receiver is then critical. The preferred alternative is a planar omnidirectional format that is integrated into the construction of the device.

Preferably, the primary control may include other devices, for example, a receiver to receive data from the implanted device. In this respect, the implanted device may be used to sense properties of its environment and then transmit such data as electromagnetic radiation to the receiver.

Accordingly, it is preferred for the antennae based device to include means to monitor predetermined conditions adjacent the antennae based device and to emit signals representative of one or more of these conditions to be received by the primary control. By way of illustration only, the device may:

(a) measure the activity of the heart in terms of a electrocardiogram; and

(b) transmit this information to the primary control.

In this way, it is possible to continuously monitor the operation of the heart and provide information to assist preventative therapies to be adopted by a person.

It is also preferred that the antennae based device may itself be a medical appliance which could operate in response to the transmitted signal. For example, the antennae based device could be a stent which is spring based where the spring acts as the antennae. This device may also be used to derive the data needed to produce a electrocardiogram as described above.

According to yet another preferred form, the antennae based device may include means to generate pulses of current. By way of illustration only, the device may:

(a) take the transmitted signal, send out pulses for muscle stimulation as specified by the signal regulating commencement time, pulse width, pulse frequency and number of pulses;

(b) measure electromyogram (EMG), pH, muscle dimensions and transmit data to the primary control;

(c) be a combination of features (a) and (b);

(d) measure the Electroencephalogram inside a cranium to detect abnormal brain conditions such as epilepsy and transmit a signal to the control to activate an alarm;

(e) send out suitable pulses in response to the condition sensed in (d) to trip the brain action back into normal activity.

In one further preferred aspect of the invention, there is provided a method for transmitting power and/or information between a first location external of a living body at which a primary control including a power source and a transmitter is located, and a second location inside the living body at which an antennae based device is located, the method comprises the steps of;

(a) generating high frequency electromagnetic radiation from the power source and emitting that radiation from the transmitter of the primary control; and

(b) receiving the radiation at the antennae based device.

In particular, the preferred range of the high frequency electromagnetic radiation is between 0.5 to 5GHz, more preferably 0.8 to 2.5 GHz.

Preferably, the method comprises the further steps of:

(c) powering the antennae based device with the radiation; and/or

(d) causing the antennae based device to generate and emit pulses of current; and/or

(e) monitoring predetermined conditions adjacent to the antennae based device and emitting signals representative of one or more of these conditions to be received by the primary control.

Whilst the following discussion is in terms of using the above system and method for stimulation purposes, it will be understood from the discussion abovethat the invention is not so limited. The invention provides a system of interaction between a location outside the living body and a location inside the living body which permits power an/or information to flow there between. The nature of the information and use of power will depend upon the antennae based device implanted in the living body.

In one particularly preferred example of the present invention, there is provided a stimulation device for providing artificial electrical stimulation, comprising a receiver antenna for receiving electromagnetic radiation from a transmitted source, a supply circuit for deriving electrical energy from the received electromagnetic radiation, an isolating circuit for isolating data signals from the received electromagnetic radiation, a pulse generator for generating electrical pulses according to the data signals utilising the electrical energy from the supply circuit, and a stimulating electrode for outputting the electrical pulses from the pulse generator.

In other words, this stimulation device comprises an antenna for receiving electromagnetic radiation from a controlled source and converting it to an oscillating current, a converter for converting the oscillating current to an electrical supply suitable to provide power for the device, an isolating circuit for separating a data signal from the oscillating current, and a pulse generator activated according to the data signal to provide electrical stimulation pulses using said electrical supply power

The stimulation device may therefore be at least substantially encapsulated in a biocompatible material, such as a suitable epoxy or the like. The stimulating electrode can be constructed from a suitable biocompatible conductive material, such as titanium. The components of the stimulation device may be contained in a single substantially encapsulated unit for ease of surgical implantation, however it is possible that the antenna and/or electrode be separate and connected to the remainder of the device by way of a short wire, for example. This construction may be desirable where the site to be stimulated by the device (i.e. the desired position of the electrode) is located relatively deep within the subject tissue. The concept of the invention would permit the antenna to be near the tissue surface for reduced attenuation of the electromagnetic radiation received at the antenna. It may additionally be desirable to provide a coating or patch of an anti reflection material on the tissue surface over the antenna to further reduce electromagnetic radiation signal attenuation.

In another version of the above illustrated form of the invention, a plurality of stimulation devices are used and are responsive to signals from a common transmission source. In this case, it is desirable for each stimulation device, or groups of stimulation devices, to be

selectively actuated by the received data signals. Accordingly, the isolating circuit or pulse generator is preferably constructed to be addressable by certain data signals, such that stimulation pulses are only generated if a certain form of data signal is received from the transmission source. For example, the stimulation device can be constructed to decode modulated digital codes and compared with predetermined codes to ascertain whether that particular device is being addressed. Alternatively, a form of frequency signal coding can be used, and the isolating circuit adapted to isolate only the data signals intended for that device. Other data encoded in the data signals can be utilised by the pulse generator to control the characteristics of electrical pulses generated, such as pulse shape, magnitude, duration and frequency.

Most patients require many devices to stimulate various muscles and sense their condition and this may be achieved by the central power source sending the signals that contain addresses of the particular electrodes to be activated or the transmitted data contains related addresses.

For example, this invention allows the patient to have the many electrodes required to stimulate walking without the fragile wires crossing joints.

In accordance with another illustration of the invention, there is provided an artificial muscle stimulation system comprising at least one stimulating electrode for providing artificial electrical stimulation to a muscle under control of an external controller, an EMG sensor for measuring EMG signals from the muscle during stimulation, a neural network processor coupled to receive the measured EMG signals to extract information regarding force of contraction and fatigue of the muscle, and wherein the external controller is coupled to an output of the neural network processor to control said artificial electrical stimulation based on said extracted information.

It has been discovered that particular muscles rapidly tire if stimulated incorrectly but this may be avoided if the muscle is stimulated in different regions or less frequently. It is useful to sense the onset of the muscle tiring and the characteristic changing voltage pattern of the contracting muscle is measured as an EMG, extension versus time, pressure between the muscle and a reference and pH. The central controller then varies the stimulation to accommodate the tiring muscle.

The new approach of the present invention in utilising an alternative power source for an implanted device to batteries which conventionally would need replacement, allows a new diversity to the facility of continuous sensing.

Description of the Drawings

The invention will now be further illustrated with reference to the accompanying drawings in which:

Figure 1 is functional block diagram of a wireless electrical muscle stimulation system according to a preferred embodiment of the present invention;

Figure 2 is a functional block diagram of a receiver and activator for a wireless FES system;

Figure 3 is a block diagram of a further preferred of the invention;

Figure 4 is a block diagram showing the construction of a digital form of the receiver activator;

Figure 5 is a block diagram of a system for providing feedback for artificial stimulation;

Figure 6 is a conceptual view of another form of the invention.

As introductory comment to the description of the drawings, a receiver and addressable activating device to enable electrical stimulation of muscles (skeletal, smooth or cardiac) is described below. This receiver is constructed to enable it to be implantable within the body of the subject, and in practice a plurality of receivers would be implanted at different locations in the body to stimulate different muscles. The receiver is also typically constructed to enable it to operate without requiring an in-built energy source. The receiver derives its energy for operation from electromagnetic radiation emanating from a transmitter. The transmitter also provides, by way of the electromagnetic signals, control commands to control the receiver and activator so as to produce appropriate electrical stimulation signals to the muscle.

To enable a wireless FES system to operate with multiple receivers/activators stimulating different muscles and to be controlled by a single transmitter, it must be able to control each receiver/activator individually. To achieve this, each receiver can be constructed to

respond only to a certain form of signal issued from the transmitter. There are various ways in which that can be implemented, including a digital addressing scheme and a frequency coded addressing scheme. Because the system is wireless, and both power and control signals are transmitted from the controller to the multiple receivers by way of electromagnetic radiation, numerous receiver/activators can be controlled using a single transmitter without the difficulties associated with implanted or even external wiring, such as wires passing through jointed areas in the body.

Each receiver includes an antenna, also implanted, tuned to receive the electromagnetic radiation from a transmitter which may be worn on or about the body of the subject. The high frequency electromagnetic signals are preferably in the range of 0.5 to 5 GHZ. A portion of the signal energy is utilised to provide electrical power to the activator circuitry, and another portion of the signal is decoded to provide control information such as the address of the receiver/activator and the shape and size of pulse to be provided at the output electrode.

This receiver/activator device is preferably encapsulated using a biocompatible epoxy. The output of the activator is a stimulating electrode which is preferably constructed of titanium or a similar biocompatible conductive material. The electrodes are self attaching or may be sutured to the muscle, and can be constructed of a form which are known in the art. The size of each output electrode may be of the order of 2 mm to 20 mm. If the muscle to be stimulated is located relatively deep inside the body, the receiving portion of the device, including the antenna, can be located near the surface and provided with a short wire link to the activating site, however it is preferable to select a frequency of the electromagnetic radiation that permits the entire device to be close to the nerve site being stimulated using electrodes on the surface of the device or very short leads to the stimulating electrodes

It may be advantageous to provide a coating or patch of an anti reflection material (suitable for the electromagnetic frequency utilised for communication between the transmitter and receiver) positioned on the skin of the subject where the receiver is located, if it is desirable to reduce the required level of radiated energy such as for the abdomen area.

Turning to the drawings, Figure 1 is a functional block diagram of a transmitter and receiver system according to one preferred form of the invention. The receiver and

activator device 10 is also illustrated in block diagram form in Figure 2. The device 10 includes a dipole antenna 12 which is constructed to receive electromagnetic signals radiated from the transmitter 2. Data signals and power is transmitted by the transmitter at frequencies which are preferably in the range of 0.5 to 5 GHz. The dipole antenna 12 can he constructed from a suitable conductive material, such as titanium, or an integrated circuit die, and may have the dimensions of, for example, 8 mm length, 4 mm width and 2 mm depth. The signals received by the antenna are passed to passive demodulating circuitry 14 of known construction. Signals of one frequency, thereby demodulated to provide an electrical power source Vbias for the activating circuitry 22, 24, 26.The electrical power provided by the output of demodulator 14 is used to charge the capacitive storage element 16.

Passive filtering circuitry 18 of conventional design can be used to isolate the control signals at carrier frequency F, which are then demodulated. The control signals provide by the output of the demodulator 20 are passed to the activator circuitry 22, 24 26.

The activation circuitry portion of the device 10 includes a digital register and comparator 22 which is able to decode the address portion of the transmitted data. The address is provided to enable selection of one single activation device or a group of devices, and a given activator may be required to be able to decode more than one address (eg one address for the particular device itself and one address for each of group of devices it may belong to). The second burst of pulses is decoded by the devices selected according to the address information, and this provides the information for that device regarding the shape and size of the pulse to be generated at the stimulating electrode. The pulse according to the received data is thus generated by the pulse generator 24, which can also be of conventional form, appears at the electrode plate 26 to stimulate the tissue it is embedded in. The electrode plate may be physically next to the rest of the receiver/activator device 10, or may be a short distance away and coupled thereto by an insulated multistrand stainless steel wire, for example. The device 10 is designed to deliver a variable current from the output electrode 26. This provides the flexibility for use in various different applications. The shape and rate of the train of pulses generated by the pulse generator is dependent on the transmitted signals, and can be dynamically controlled by the external controller to meet the muscle recruitment requirements. This flexibility is useful in order to

be able to have a control over the recruitment of motor units. This is a feature that the existing stimulators have not been able to offer.

Another illustration of the invention is shown in block diagram form in Figure 3, in which the appropriate activating device is addressed by a choice of modulating tones which is decoded by means of band pass filters 28. In this case, the duration of the tone can be used to determine the width of the pulse to be output by the pulse generator 24. The pulse then appears at the electrode plate 26 and drives a current stimulus through the tissues it is embedded in. Once again, the electrode plate may be physically next to the remainder of the activator device or may be a short distance away and coupled thereto by an insulated multistrand SS wire, for example.

Figure 4 illustrates in block diagram form a digital implementation of the receiver/activator 30, in which the functions of the signal filtering, demodulation, address decoding and pulse generation are all performed by a single integrated microprocessor and A/D converter circuit 34. The power for the circuit 34 is provided by the power supply circuit 32, which operates in the same manner as described hereinabove, deriving usable electrical current from the electromagnetic radiation received at the receiver antenna 12. The functions of the microprocessor and A/D converter circuit are controlled by, for example, micro-coded computer program instructions in a known way. The stimulations pulses to the electrodes 26 are driven directly from the integrated circuit, and this diagram also illustrates the possibility of driving: more than one electrode from a single receiver.

Features of the device described herein include the simple construction which makes it robust and immune to the traumatic environment existing inside the body. There are no coils in the device since inductive coupling is avoided. There are no chemical reactions which may occur in devices which have charge storage bimetallic capacitors. Lengthy wires are not required, which makes the surgical implantation procedures very simple. The device characteristics do not change if there is tissue growth, and a controllable pulse duration and stimulating current is provided for. This is useful in case where the muscle characteristics were to change whether over a long duration of time (eg through aging) or over a short duration (such as through muscle fatigue).

Because the system of the present invention do not require wired connections from the control device, numerous antennae based devices (eg stimulator devices) can be implanted without the difficulties associated with the wires bypassing joints in the subject. For example, it is estimated that a minimum of perhaps 50 separate artificial stimulators would be required to fully restore a walking function in a subject with disabled motor functions to the legs, and wires to that many stimulator sites would be very problematic. The present invention provides a system which can, however, easily accommodate that number of receiver/activators, with each individually addressable or addressable in selected groups. For example, with addressing of the receivers by respective digital codes, an eight bit code would enable selective activation of256 devices and/or groups of devices.

In conjunction with FES stimulation, one further preferred aspect of the present invention also envisages a system which includes an EMG recorder, an intelligent signal processor and an artificial stimulation controller. The purpose of this overall system is to be able to control the muscle stimulation pattern in order to provide near natural muscle contraction for subjects with neuromotor control disorder. As such this embodiment incorporates the following features:

(a) EMG measurement from the muscles under stimulation to provide feedback for controlling the artificial stimulation;

(b) processing the EMG measurements using neural network processing to extract information relating to muscle fatigue and force of muscle contraction.

(c) the ability to control the muscle stimulation based on the muscle fatigue status and the net force of contraction being produced by the muscle.

The above features can be implemented in the following manner:

(a) Neural Networks and Time frequency atoms have been used in past to analyse EMG. (Englehart K et al, "Classification of Myoelectric Signal Burst Patterns Using A Dynamic Neural Network", IEEE 1995; Hiraiwa A et al, Shimohara K and Tokunga Y, "EMG Pattern Analysis and Classification by Neural Network" IEEE 1989; Jang GC, Cheng FHY, Lai JS and Kuo TS "Using Time Frequency Analysis Technique in the Classification of Surface Emg Signals", IEEE 1994). The present

system utilises similar techniques to analyse EMG of the FES stimulated muscles for the purpose of having a closed loop FES system.

(b) During a training phase which is performed under supervision, a fixed stimulation pattern is applied to different electrodes in the same muscle. EMG recordings are memorised by the neural network against the muscle contraction pattern. The system learns the correlation of the EMG signal, force and fatigue. Fatigue is also taught to a parallel system with the help of the spectrum of the signal.

(c) Thereafter, the system stimulates the same muscle with the help of different pulse shapes and amplitudes and records the force of contraction. The system is self learning and this can continue even when the stimulating device is implanted. The system incorporates nested neural networks. The network learns the correlation between time, wave shape and strength of contraction.

(d) The trained system receives the EMG signal from the muscles being stimulated. The system works in a closed loop and with the help of training, it correlates time EMG wave shape and spectrum with force of contraction and fatigue. The system then changes the pulse shape and rate of muscle stimulation in order to achieve a constant muscle contraction. The system is thus able to predict and compensate for the muscle fatigue. By suitably selecting a various different sets of electrodes in the same muscle, motor recruitment can therefore be altered and muscle fatigue prevented or reduced.

An example of an implementation of such as system 40 is illustrated in block diagram form in Figure 5. In the system 40 a stimulation controller 42 is used to artificially stimulate the subject's muscle 54 by way of FES electrodes 52 in order to achieve muscle contraction in the subject. EMG sensors 48 measure EMG feedback signals from the muscle, which are passed to an analyser circuit 46 and thence to a neural network processor 44. The neural network processor 44 provides electrical feedback to the stimulation controller 42 according to discerned muscle fatigue, etc. A joystick 50 or the like, under control of the subject, can provide physical feedback signals indicative of, for example, muscle contraction. The above described system thus enables a technique for processing surface EMG using intelligent signal processing techniques incorporating Neural Networks. The

technique extracts information related to the status of muscle fatigue and force of the stimulated muscle. The system can therefore provide information related to change in motor recruitment and stimulation in order to maintain constant force of contraction and prevent fatigue. It can also analyse the need by the subject to increase or decrease the force of contraction of any muscle.

With reference to figure 6, the controller emits a signal to an implanted device in a leg. The implanted device takes the transmitted signal, decodes it, sends out pulses for muscle stimulation as specified by the signal regulating commencement time, pulse width, pulse frequency and number of pulses. As shown the device also includes a sensor to measure characteristics such as EMG, pH, and muscle dimensions. It then transmits data to the controller. In this way, the system provides a remotely powered device that can be instructed to stimulate muscles and also monitor the state of the muscles.

It is to be understood by those skilled in the technology that many variations or modifications in details of design or construction may be made without departing from the essence of the present invention. Therefore, the invention should be understood to include all such variations and modifications within its scope.

The word 'comprising' as used in this description does not limit the invention claimed to exclude any variants or additions which are obvious to the person skilled in the art and which do not have a material effect upon the invention.

Wolfe Research Pty Ltd **22 September, 1998**

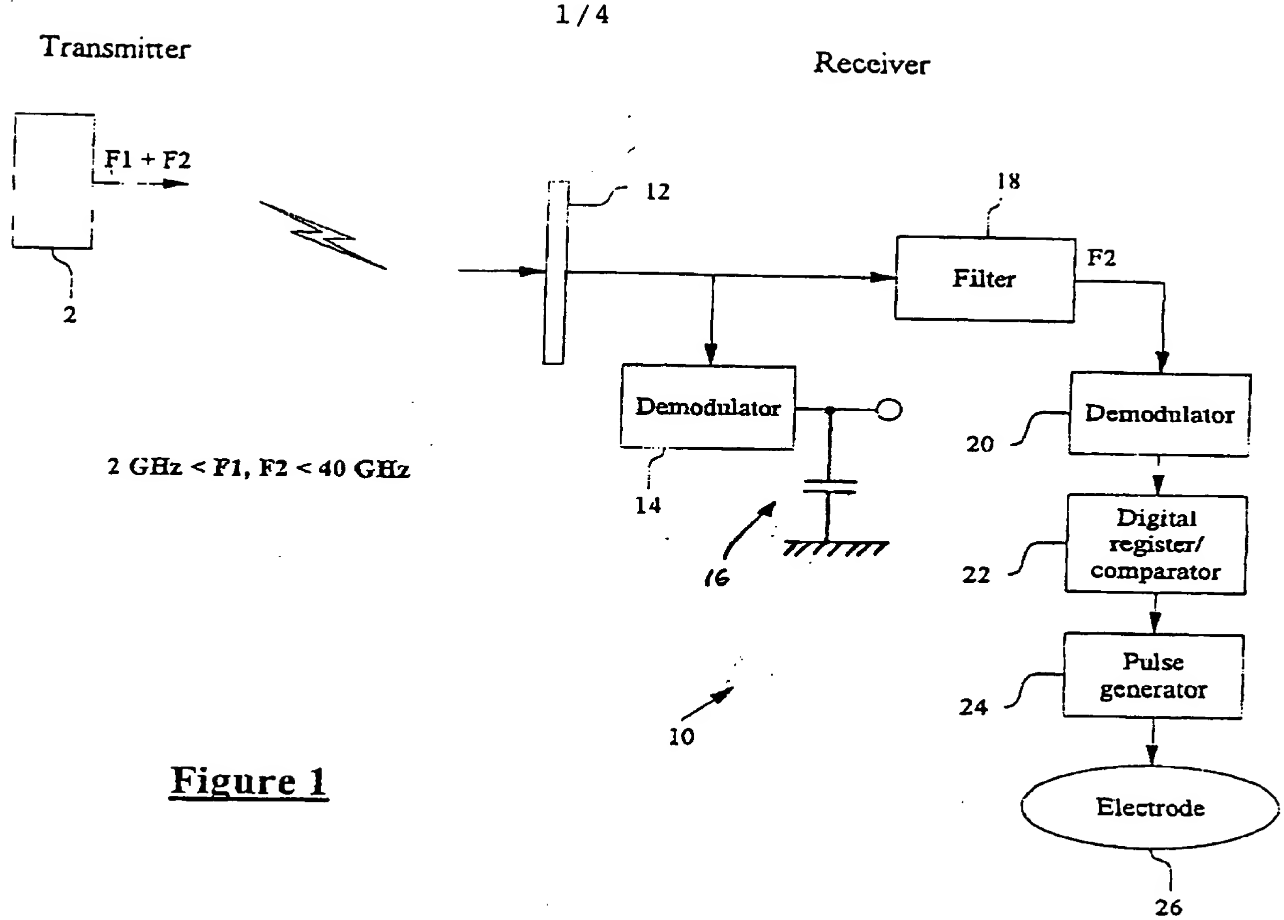

Figure 1

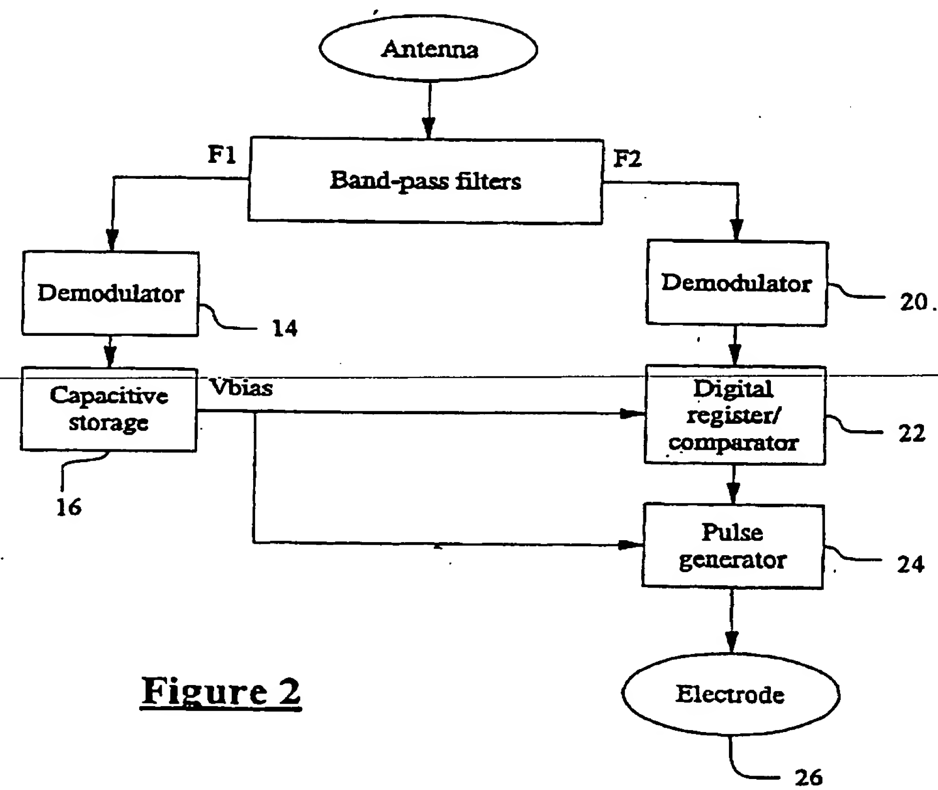

Figure 2

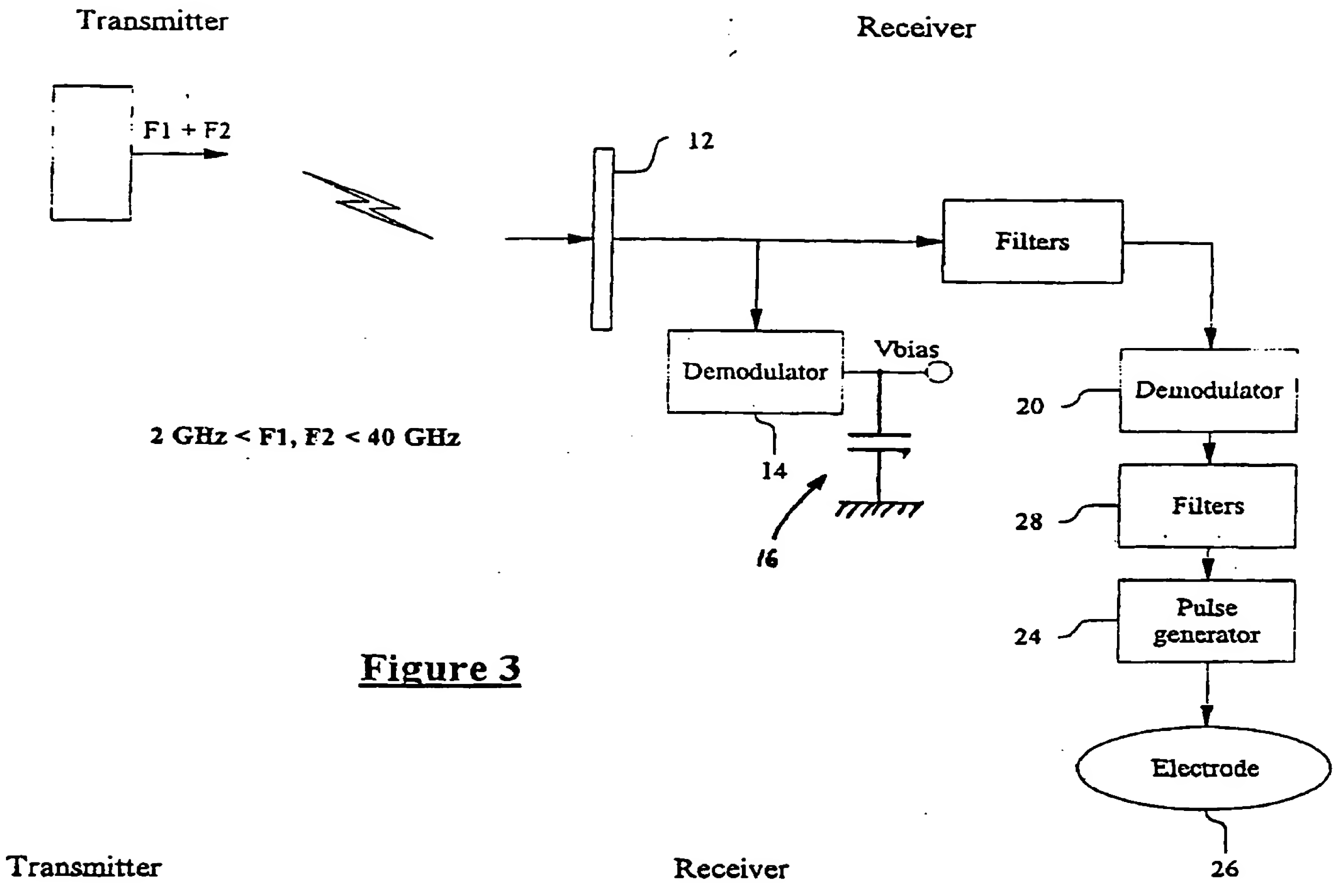

Figure 3

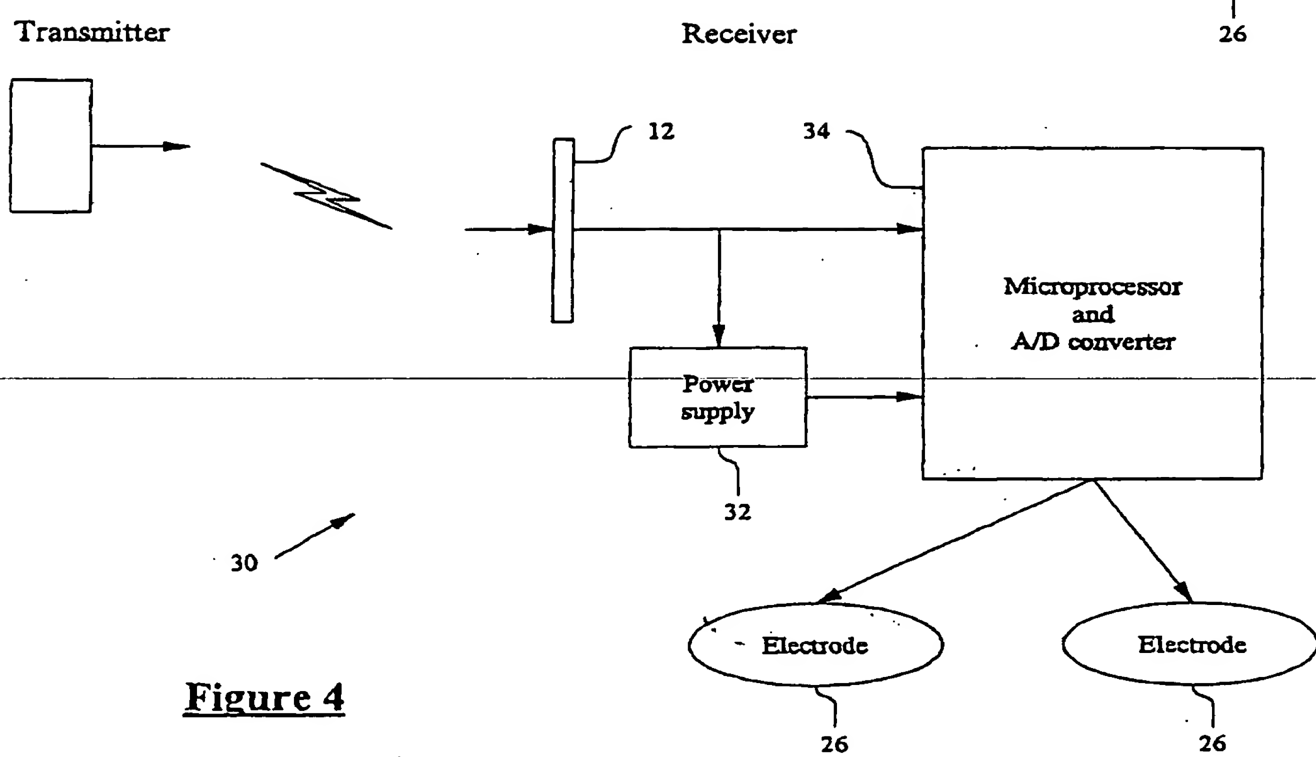

Figure 4

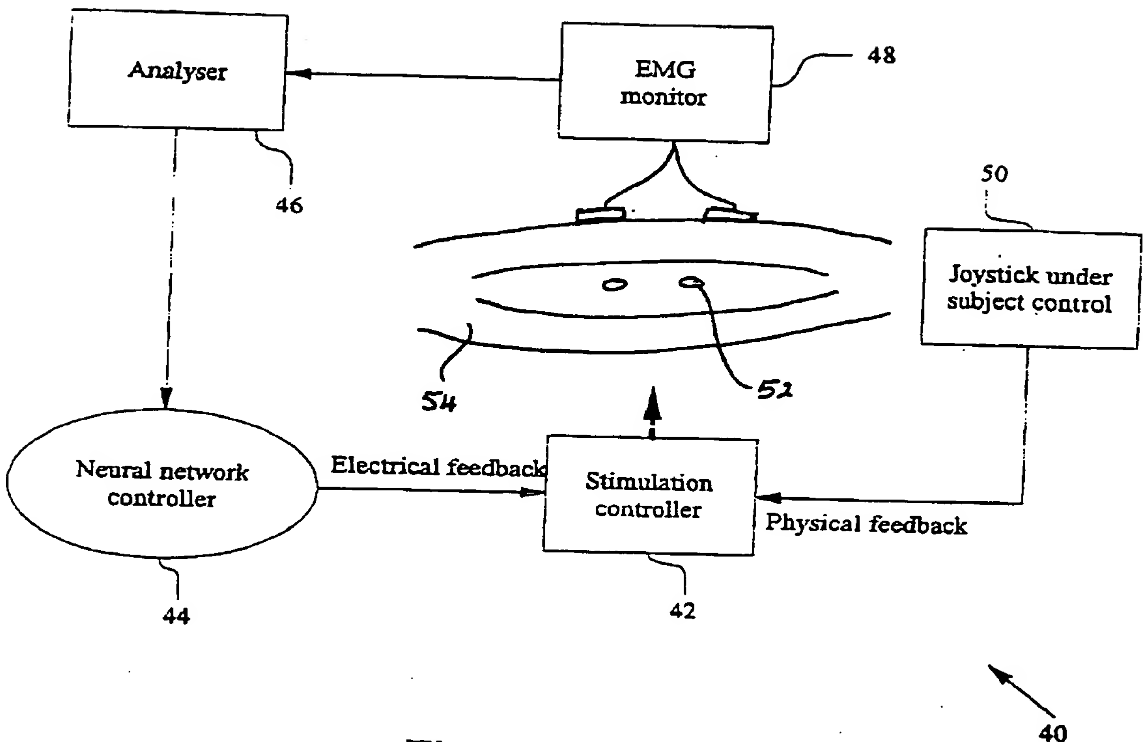
Analyser
EMG monitor
48
46
50
Joystick under subject control
54
52
Neural network controller
Electrical feedback
Stimulation controller
Physical feedback
44
42
40

Figure 5

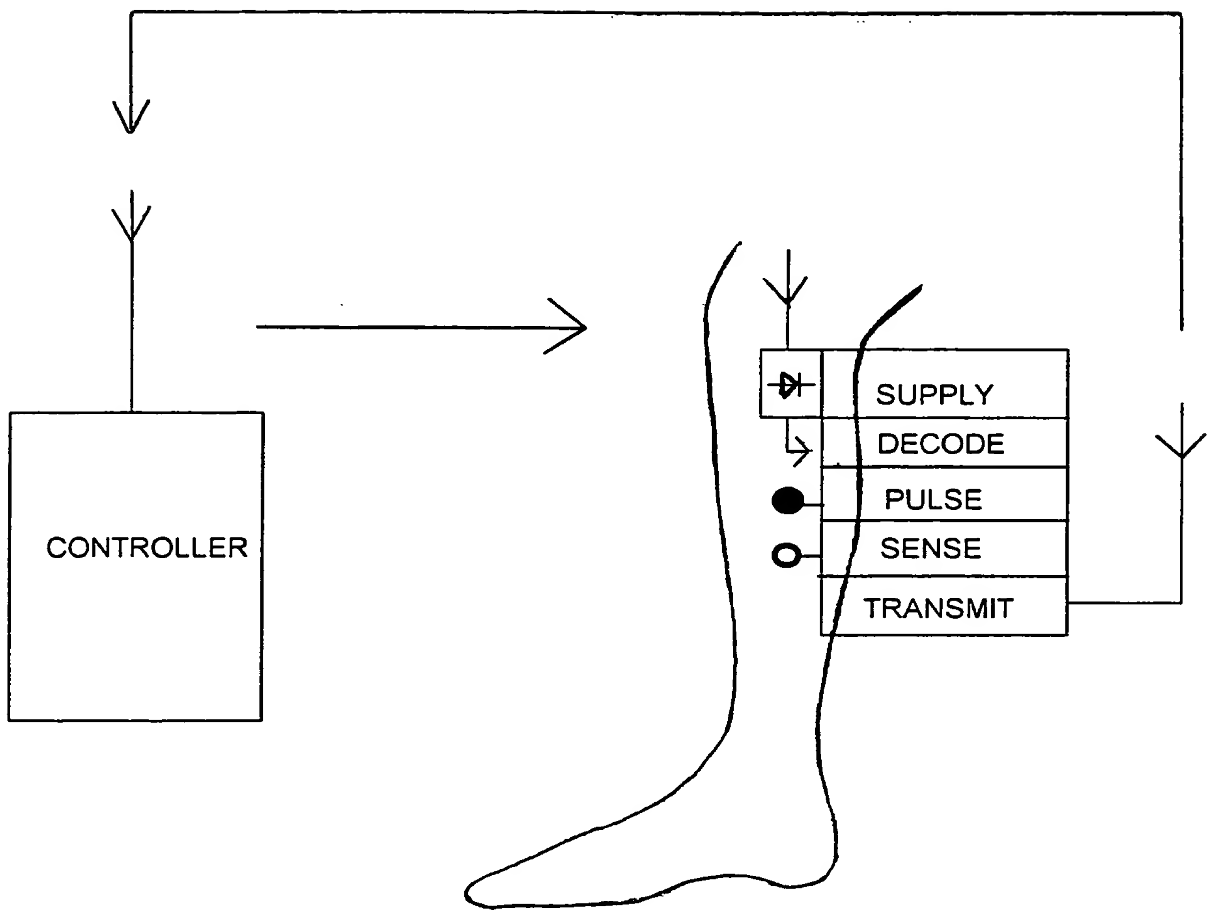

FIGURE 6